UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

ACELLA PHARMACEUTICALS, LLC, Plaintiff, v. ANI PHARMACEUTICALS, INC., Defendant.	Case No.: **COMPLAINT** **JURY DEMANDED**

Plaintiff Acella Pharmaceuticals, LLC ("Acella"), for its Complaint against Defendant ANI Pharmaceuticals, Inc. ("ANI" or "Defendant"), alleges as follows:

NATURE AND BASIS OF THE ACTION

1. This case concerns Acella's prescription-only natural desiccated thyroid (NDT) therapy, NP Thyroid® (thyroid tablets, USP), and Defendant ANI's efforts to take NP Thyroid® sales through a campaign of literally false and misleading advertising. Naturally derived from porcine thyroid glands, the active ingredients in Acella's NP Thyroid® provide levothyroxine (sometimes referred to as "T4") and liothyronine (sometimes referred to as "T3"), in multiple dosage strengths (including 30 mg, 60 mg, and 90 mg). Doctors prescribe NP Thyroid® to help patients address and overcome the debilitating effects of hypothyroidism. Acella rigorously tests its finished product to ensure strict compliance with United States Pharmacopeia (USP) standards. As a result of NP Thyroid®'s quality and Acella's efforts, NP Thyroid® is a leading NDT thyroid treatment option in the U.S.

2. Seeing an opportunity for profits at the expense of patients, ANI launched a competing "generic" product, "Thyroid Tablet USP," also in 30 mg, 60 mg, and 90 mg dosages (hereinafter collectively, ANI's "Generic Thyroid Tablets"). ANI labels and advertises its Generic Thyroid Tablets as providing exactly the same active ingredients in exactly the same strengths as NP Thyroid®, in order to have pharmaceutical databases and customers "link" the ANI Generic Thyroid Tablets as a generic alternative for Acella's NP Thyroid®. ANI also labels and advertises that its Generic Thyroid Tablets satisfies USP's quality standards, making this claim in the very name of its products: "**Thyroid Tablets USP**."

3. ANI's advertising is literally false and misleading. To satisfy USP's standards, ANI's Generic Thyroid Tablets would have to provide at least 90% (and no more than 110%) of its labeled active ingredients, including levothyroxine, throughout the product's labeled shelf-life. But testing by a third-party laboratory demonstrates that ANI's Generic Thyroid Tablets—across the 30 mg, 60 mg, and 90 mg dosage strengths—does not contain its labeled strength during even a fraction of its shelf-life and does not satisfy USP's minimum standards. In short, ANI's Generic Thyroid Tablets does not provide what ANI's label advertises.

4. ANI's Generic Thyroid Tablets does not contain what it is advertised to contain, it is not USP-compliant, and it is not a generic for NP Thyroid®, as ANI's advertising falsely and misleadingly states and implies. ANI's false advertising is potentially devastating to patients, who purchase and take this inferior drug product rather than Acella's NP Thyroid®. ANI's literally false advertising also injures Acella, which is

losing sales and market share due to ANI's false advertising and unfair competition. Acella brings this action under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and Minnesota state law to put an end to ANI's false and misleading advertising, and for just compensation for the injuries ANI caused.

PARTIES

5. Acella is a limited liability company formed under the laws of the State of Delaware, with its principal place of business in Alpharetta, Georgia. A specialty pharmaceutical company founded in 2008, Acella is committed to accelerating health care solutions by bringing quality, affordable products to customers and patients. Acella markets NP Thyroid® in Minnesota and throughout the United States.

6. ANI is a publicly-traded corporation organized under the laws of Delaware, with its principal place of business at 210 Main Street West, Baudette, Minnesota 56623. ANI markets its Generic Thyroid Tablets in Minnesota and throughout the United States.

JURISDICTION AND VENUE

7. Acella brings this action under § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and this Court has original subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1338 (unfair competition); *see also* 15 U.S.C. §§ 1116 & 1121 (providing this Court original jurisdiction over Lanham Act claims and claims for injunctive relief under the Lanham Act). The Court may exercise supplemental jurisdiction over Acella's state law claims pursuant to 28 U.S.C. § 1367(a) because they are related to Acella's Lanham Act claims such that they form the same case or controversy.

8. ANI's principal place of business is in Minnesota, and venue is proper in this

Court under 28 U.S.C. § 1391(b).

9. The exercise of personal jurisdiction in Minnesota is proper because ANI's principal place of business is in Minnesota, and because acts giving rise to Acella's causes of action have occurred in this District. Specifically, ANI markets, promotes, advertises, offers for sale, sells, and/or distributes its Generic Thyroid Tablets to customers, including drug wholesalers, retail pharmacy chains, and others, throughout the United States, including in the District of Minnesota.

FACTUAL BACKGROUND

A. Hypothyroidism and Natural Desiccated Thyroid

10. It is estimated that millions of Americans (over 4% of our population) suffer from hypothyroidism, a condition resulting from decreased production of thyroid hormones—principally levothyroxine and liothyronine. The symptoms of hypothyroidism may include fatigue, weakness, bradycardia (a slower-than-normal heart rate), depression, and problems with memory, among others. If left untreated, the condition can lead to goiters (an enlarged thyroid gland), infertility, birth defects, peripheral neuropathy, and even death following myxedema coma.

11. The standard of care for treating this serious condition often includes prescription thyroid replacement therapy—using either synthesized or naturally-derived thyroid hormones to supplement what the patient's body no longer produces. Natural Desiccated Thyroid (NDT) derived from porcine thyroid glands harvested from pigs and hogs represents a key source of the active pharmaceutical ingredient (API) used in natural thyroid replacement therapy.

12. Producing a high-quality natural thyroid replacement option depends on formulating it with a consistent and high-quality API. And for this reason, the consistency and quality of the livestock from which NDT ingredients are harvested are critical. Pigs and hogs raised for this specific purpose are selected from carefully bred lines, raised in well-controlled conditions, and harvested in regulated and inspected facilities. This, however, is not consistently true for NDT ingredients imported from China, which may be derived from inconsistent, low quality raw materials harvested from heterogenous animals raised in suboptimal conditions across many different farms and processed without the quality control measures that are standard in the United States.

13. The FDA recognizes that: "Manufacturing DTE [desiccated thyroid extract, another term for NDT] from pig glands tends to be a more complex process, and may result in safety, effectiveness, and quality issues because of inconsistent and inaccurate doses." https://www.fda.gov/consumers/consumer-updates/older-therapies-arent-necessarily-better-thyroid-hormone-replacement. The FDA has acted on these concerns in addressing potentially dangerous and non-compliant NDT imported from abroad.

14. For example, in 2018, FDA issued a Warning Letter to Sichuan Friendly Pharmaceutical Co., Ltd., based in China. As FDA observed in a subsequent statement specifically with respect to Sichuan Friendly's NDT ingredient:

> FDA laboratory testing confirmed the Sichuan Friendly API has inconsistent levels of the active ingredients – levothyroxine and liothyronine – **and should not be used to manufacture or compound drugs for patient use**.

https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-drug-makers-recall-porcine-thyroid-api-sichuan-friendly-pharmaceutical-co-limited-china (emphasis added).

15. Only a few weeks ago, FDA issued a similar warning letter to another Chinese manufacturer, Sichuan Deebio Pharmaceutical Co., Ltd., which had recently begun importing a substantial volume of NDT into the United States. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sichuan-deebio-pharmaceutical-co-ltd-669808-02052024. Among other problems, FDA noted significant concerns about "the validity and integrity of [Sichuan Deebio's] laboratory testing records." FDA warned that, "[b]ecause [Sichuan Deebio's] methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, [its] API [active pharmaceutical ingredients] are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)."

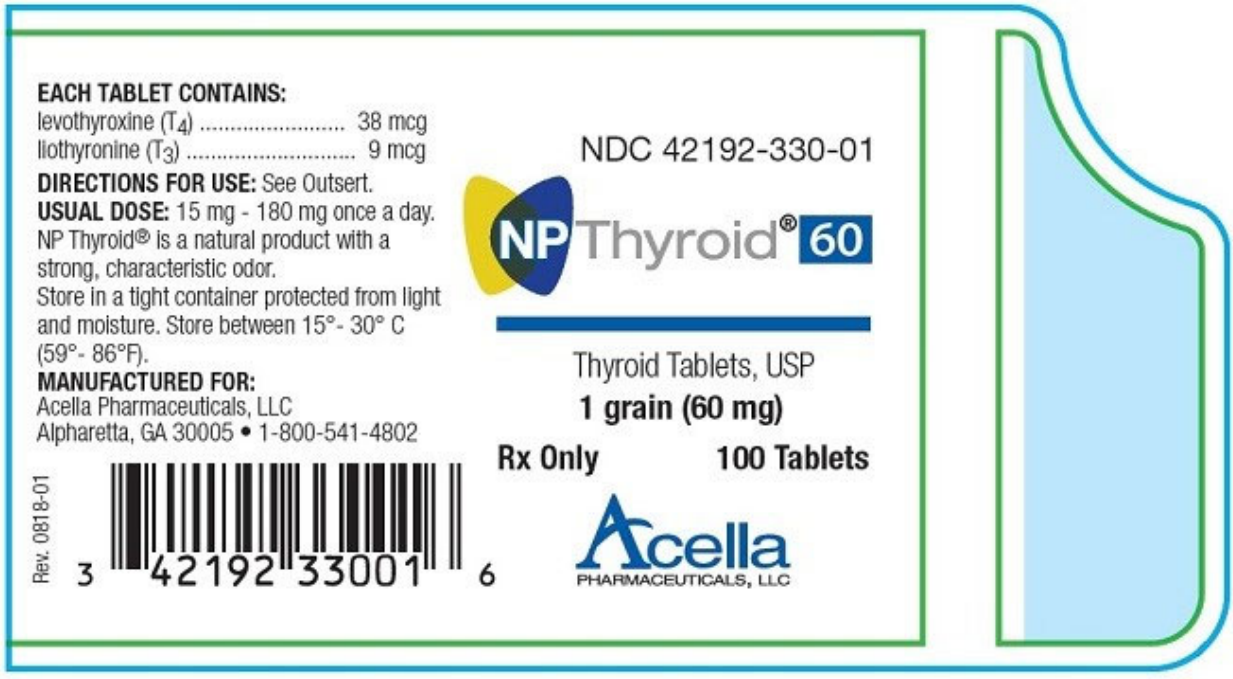
B. Acella's NP Thyroid®

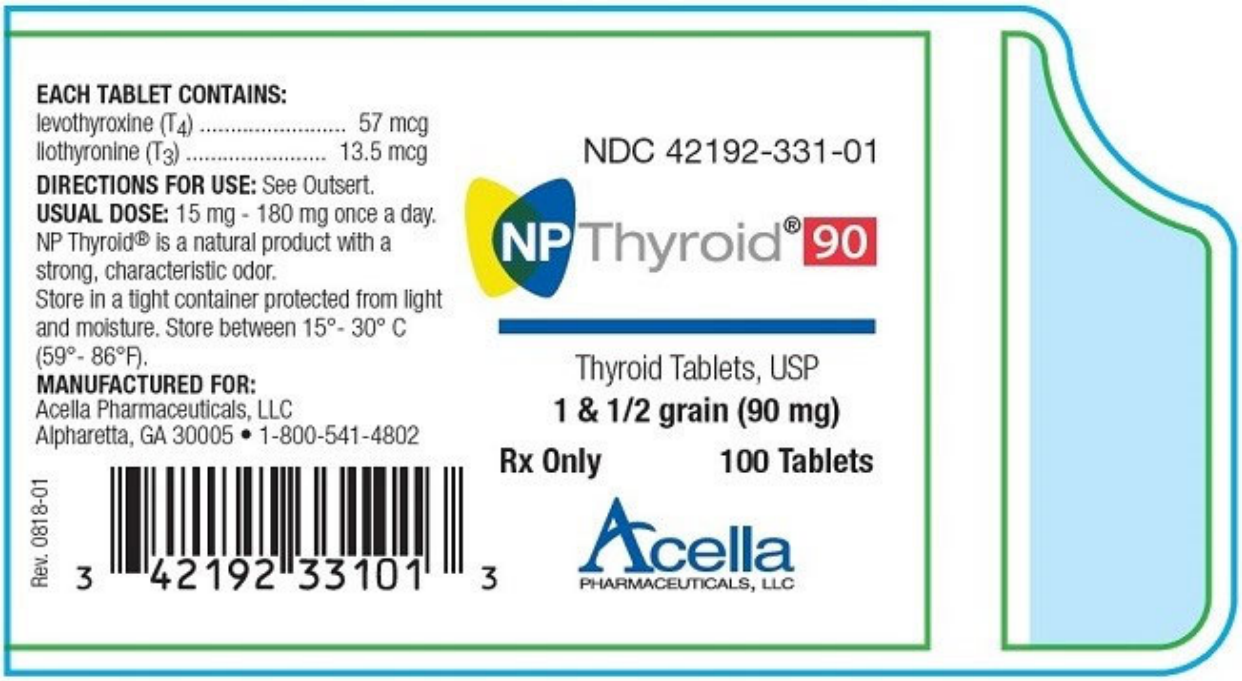
16. Acella launched NP Thyroid® in 2010, and over the years, NP Thyroid® has become a leading natural thyroid replacement treatment option in the United States.[1]

17. Acella manufactures NP Thyroid® in the United States, using API sourced from an FDA regulated and inspected facility in Spain. Acella offers NP Thyroid® in several dosages, including 30 mg, 60 mg, and 90 mg. Acella rigorously tests NP Thyroid® to ensure it fully complies with USP standards, and labels its product accordingly:

[1] Acella's NP Thyroid® also may be prescribed as a thyroid-stimulating hormone ("TSH") suppressant, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter, and in the management of thyroid cancer. It may also be prescribed as a diagnostic agent in suppression tests to differentiate suspected mild hyperthyroidism or thyroid gland autonomy.


EACH TABLET CONTAINS:
levothyroxine (T_4) ..... 19 mcg
liothyronine (T_3) ..... 4.5 mcg
DIRECTIONS FOR USE: See Outsert.
USUAL DOSE: 15 mg - 180 mg once a day.
NP Thyroid® is a natural product with a strong, characteristic odor.
Store in a tight container protected from light and moisture. Store between 15°- 30° C (59°- 86°F).
MANUFACTURED FOR:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30005 • 1-800-541-4802
Rev. 0818-01
3 42192 32901 0
NDC 42192-329-01
NP Thyroid® 30
Thyroid Tablets, USP
1/2 grain (30 mg)
Rx Only
100 Tablets
Acella PHARMACEUTICALS, LLC

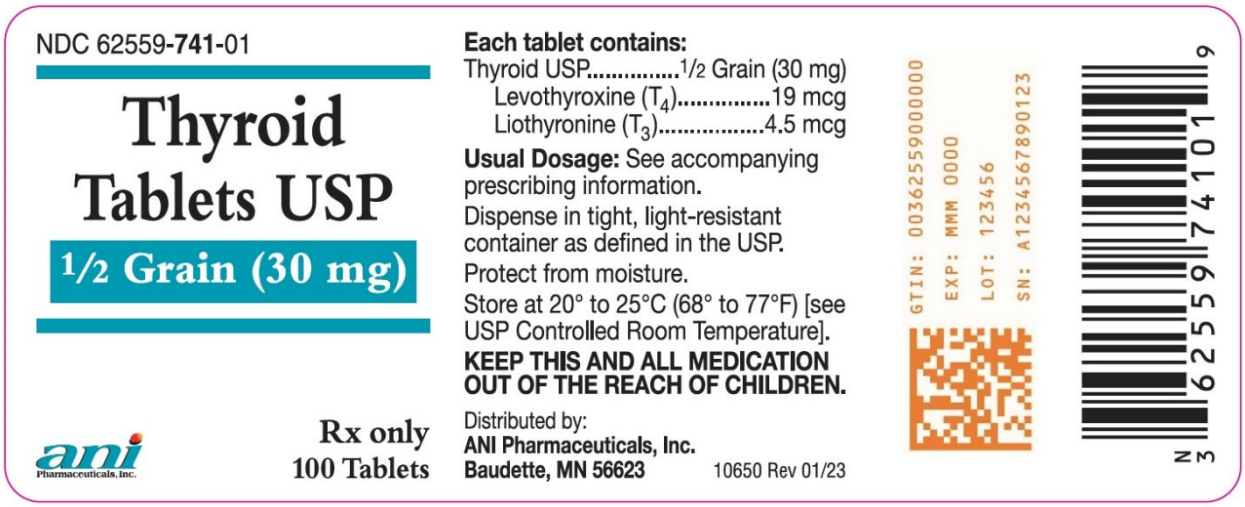

EACH TABLET CONTAINS:
levothyroxine (T_4) ..... 38 mcg
liothyronine (T_3) ..... 9 mcg
DIRECTIONS FOR USE: See Outsert.
USUAL DOSE: 15 mg - 180 mg once a day.
NP Thyroid® is a natural product with a strong, characteristic odor.
Store in a tight container protected from light and moisture. Store between 15°- 30° C (59°- 86°F).
MANUFACTURED FOR:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30005 • 1-800-541-4802
Rev. 0818-01
3 42192 33001 6
NDC 42192-330-01
NP Thyroid® 60
Thyroid Tablets, USP
1 grain (60 mg)
Rx Only
100 Tablets
Acella PHARMACEUTICALS, LLC

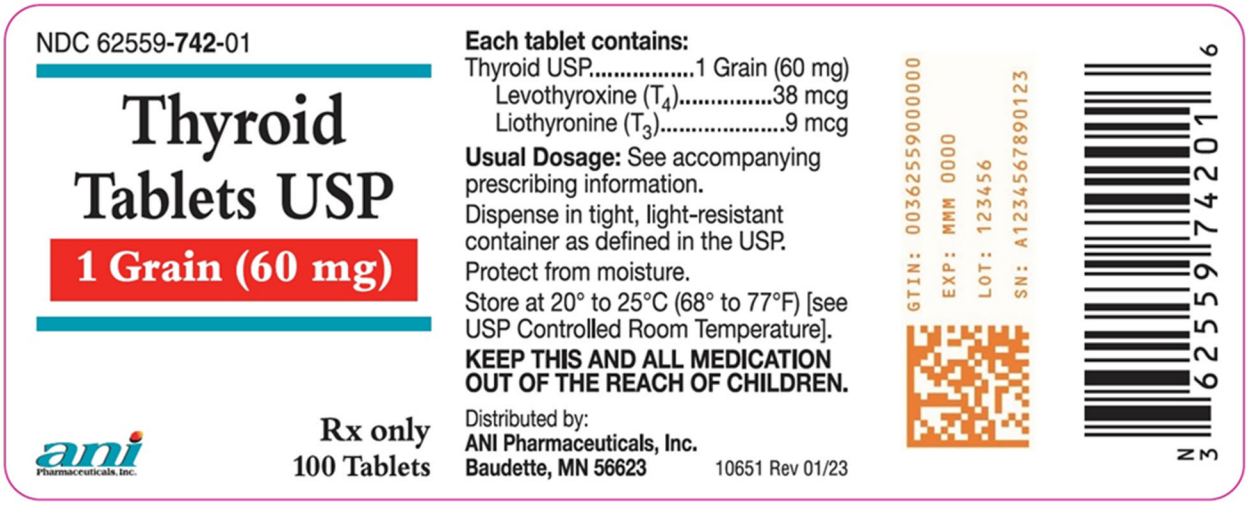


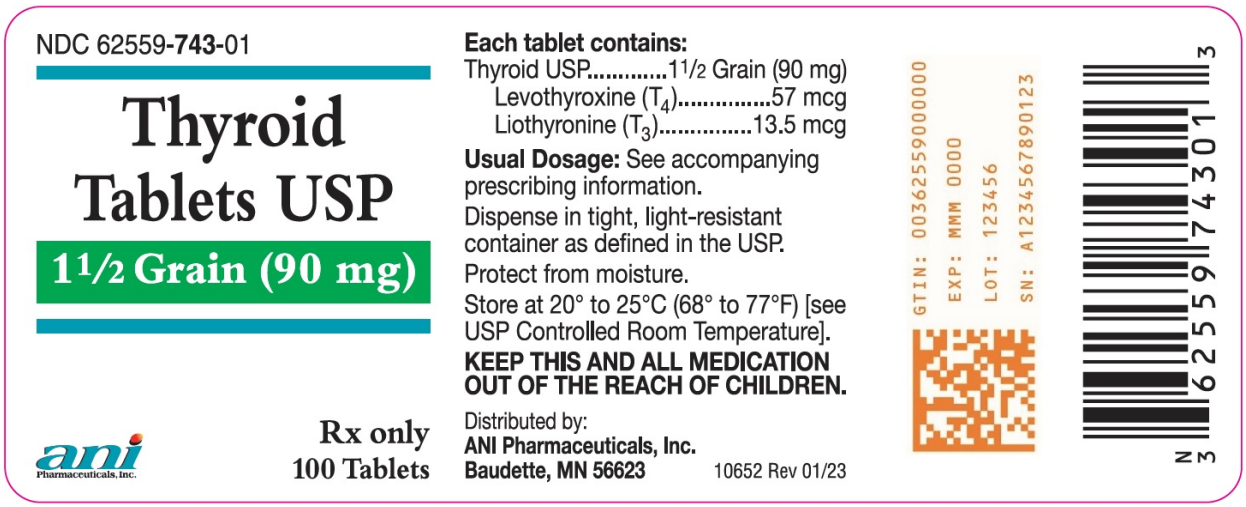
Each dosage of NP Thyroid® is formulated with an approximately 4.22 to 1 ratio of levothyroxine to liothyronine. While both active ingredients have a role in treating hypothyroidism, levothyroxine is formed only in the thyroid gland; it is not formed anywhere else in the body. In contrast, liothyronine is created both in the thyroid gland and other organs. Thus, a key function of thyroid replacement therapy is ensuring a supplement of the levothyroxine that the patient's own thyroid cannot produce.

C. ANI's Generic Thyroid Tablets

18. ANI describes itself as "an integrated specialty pharmaceutical company," and claims to market both generic and brand products. In 2023, ANI launched its Generic Thyroid Tablets as a generic, calling it "Thyroid Tablet USP." ANI markets its Generic Thyroid Tablets in the same three strengths as NP Thyroid®, and labels and advertises those products as containing the identical amounts of levothyroxine and liothyronine as their NP Thyroid® counterparts:


NDC 62559-741-01
Thyroid Tablets USP
1/2 Grain (30 mg)
Each tablet contains:
Thyroid USP.....1/2 Grain (30 mg)
Levothyroxine (T4).....19 mcg
Liothyronine (T3).....4.5 mcg
Usual Dosage: See accompanying prescribing information.
Dispense in tight, light-resistant container as defined in the USP.
Protect from moisture.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.
Rx only
100 Tablets
Distributed by:
ANI Pharmaceuticals, Inc.
Baudette, MN 56623
10650 Rev 01/23
GTIN: 00362559000000
EXP: MMM 0000
LOT: 123456
SN: A123456789123
N 362559741019


NDC 62559-742-01
Thyroid Tablets USP
1 Grain (60 mg)
Each tablet contains:
Thyroid USP.....1 Grain (60 mg)
Levothyroxine (T4).....38 mcg
Liothyronine (T3).....9 mcg
Usual Dosage: See accompanying prescribing information.
Dispense in tight, light-resistant container as defined in the USP.
Protect from moisture.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.
Rx only
100 Tablets
Distributed by:
ANI Pharmaceuticals, Inc.
Baudette, MN 56623
10651 Rev 01/23
GTIN: 00362559000000
EXP: MMM 0000
LOT: 123456
SN: A123456789123
N 362559742016


NDC 62559-743-01
Thyroid Tablets USP
1 1/2 Grain (90 mg)
Each tablet contains:
Thyroid USP.....1 1/2 Grain (90 mg)
Levothyroxine (T4).....57 mcg
Liothyronine (T3).....13.5 mcg
Usual Dosage: See accompanying prescribing information.
Dispense in tight, light-resistant container as defined in the USP.
Protect from moisture.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.
Rx only
100 Tablets
Distributed by:
ANI Pharmaceuticals, Inc.
Baudette, MN 56623
10652 Rev 01/23
GTIN: 00362559000000
EXP: MMM 0000
LOT: 123456
SN: A123456789123
N 362559743013

D. USP Is An Official Compendial Standard

19. Like Acella's NP Thyroid®, ANI labels and advertises its Generic Thyroid Tablets as satisfying the standards of the United States Pharmacopeia (USP). The USP is a standards-setting organization, recognized as an "official compendium" for drugs marketed in the United States. 21 U.S.C. § 321(j).

20. Any drug marketed in the United States with a name recognized in the USP **must** conform to USP standards. Title 21 U.S.C. § 351(b) ("Strength, Quality, or Purity Differing From Official Compendium") provides:

> A drug or device shall be deemed to be adulterated . . . If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.

See also 21 C.F.R. § 299.5 (Drugs; compendial name).

21. The USP has long recognized Thyroid Tablets which are described in a USP monograph, most recently published in USP 40. *See* Second Suppl. to USP 40-NF 35. Among the USP's mandatory quality standards, a compliant thyroid tablet must have **not less than 90.0%** and not more than 110.0% of the labeled amounts of levothyroxine and liothyronine active ingredients throughout the tablet's labeled shelf-life.

E. ANI's Labeling, Advertising, and Promotion Of Its Generic Thyroid Tablets

22. Patients taking NP Thyroid® or ANI's Generic Thyroid Tablets must first obtain a prescription from their doctors, and then obtain their thyroid tablet product through a pharmacy (either retail or on-line). ANI, however, does not market its Generic Thyroid Tablets under a brand name, and on information and belief, does not promote its Generic

Thyroid Tablets to doctors. Accordingly, on information and belief, doctors do not write prescriptions for ANI's Generic Thyroid Tablets. Instead, doctors write prescriptions for brand-name thyroid tables, notably including NP Thyroid®, and pharmacists dispense to patients—and those patients then purchase—ANI's Generic Thyroid Tablets as a result of **pharmacist substitution**.

23. A pharmacist presented with a doctor's prescription may fill it by dispensing the brand product actually named in the prescription, or by substituting an equivalent, "generic" version of the brand. A "generic" drug is "[a] prescription drug that has the same active-ingredient formula as a brand-name drug." https://www.healthcare.gov/glossary/generic-drugs/; *see also* https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#G ("A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use."); https://www.health.state.mn.us/facilities/insurance/managedcare/faq/pharmacy.html ("There is no difference in the active ingredients between a brand name drug and its generic equivalent."); *accord*, *Elorac, Inc. v. Henson*, No. 16-cv-11522, 2017 WL 5957195, at * (N.D. Ill. Mar. 13, 2017) ("A minimum standard for appropriate generic substitution of products at the pharmacy level is 'pharmaceutical equivalence.' Products are considered to be pharmaceutical equivalents if they contain the same ingredient(s) and the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration."); *Axcan Scandipharm Inc. v. Ethex Corp.*, 585 F. Supp. 2d 1067, 1074 n.8 (D. Minn. 2007) (defining pharmaceutical equivalence).

24. To market its Generic Thyroid Tablets as a generic for NP Thyroid®, ANI

advertises its product as matching, exactly, NP Thyroid®'s active ingredients and strengths (including the identical amounts of levothyroxine and liothyronine). There is no regulatory, chemical, pharmaceutical, compendial, or medical requirement or necessity that it do so. Instead, ANI copied NP Thyroid®'s labeling information—and claimed to offer an identical product as NP Thyroid®—to capture sales that should have gone to Acella for NP Thyroid®.

25. ANI communicated with national drug information databases, including Medi-Span® (a Wolters Kluwer company) and First DataBank (a Hearst Health company), to ensure that ANI's labeling, advertising, and promotion of its Generic Thyroid Tablets as a generic for NP Thyroid®, and as a product providing exactly the same active ingredients in exactly the same amounts as NP Thyroid®, and as USP-compliant, would reach customers and potential customers in the pharmaceutical supply chain. These customers include pharmaceutical wholesalers (e.g., McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health), and drug retailers (e.g., CVS, Walgreens, and Wal-Mart). It is through this supply chain that ANI's Generic Thyroid Tablets ultimately is dispensed and sold to patients in lieu of NP Thyroid®.

26. Relying on the information provided by distributors like Acella and ANI, Medi-Span®, First DataBank, and other drug information databases like "link" apparently equivalent products to each other. Pharmaceutical wholesalers, retail pharmacy chains, and others in the pharmaceutical supply chain use this linkage information to determine whether a generic is available for a particular branded prescription drug.

27. ANI succeeded in convincing drug databases, including Medi-Span®, to link

its Generic Thyroid Tablets to NP Thyroid® as a pharmaceutically equivalent product, with an advertised cost savings of about 5%:

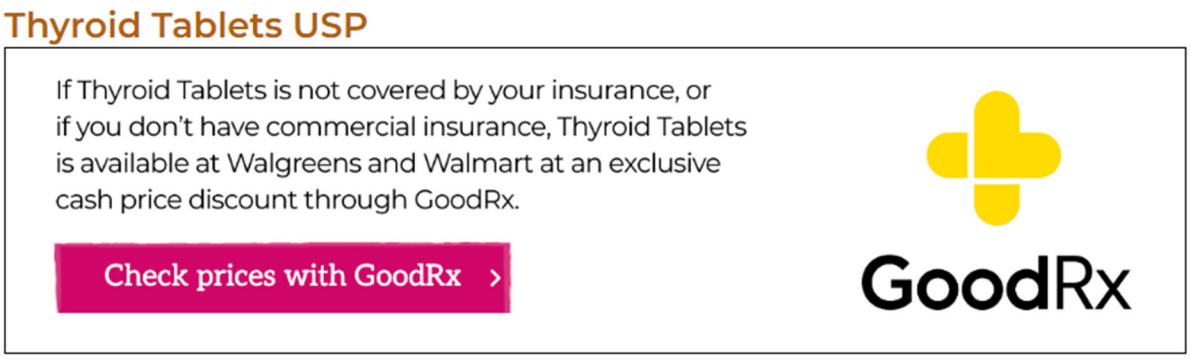
NDC/UPC/HRI	Product Name	Package Size	Package SUM	Package Qty	Package Description	Labeler Name	Labeler Code
62559-0742-01	Thyroid Oral Tablet 60 MG	100 EA		1 Bottle		ANI PHARMACEUTICALS	62559

GPI Cross Reference - Thyroid Tab 60 MG (1 Grain) (28-10-00-50-00-03-15) - Package Size 100

NDC/UPC/HRI	Product Name	AWP	DP	WAC	ACA FUL	AAWP	GEAP	AWAC	GEWAC	Labeler	MS	TEE	Rx
00456-0459-01	Armour Thyroid Oral Tablet 60 MG	$128.33	$106.94	$106.94		$0.00		$0.00		ALLERGAN	N	NR	R
42192-0330-01	NP Thyroid Oral Tablet 60 MG	$116.11		$76.39		$0.00		$0.00		ACELLA PHARMACEUTICALS	N	NR	R
50090-0190-00	Armour Thyroid Oral Tablet 60 MG	$110.86								A-S MEDICATION SOLUTIONS	N	NR	R
62559-0742-01	Thyroid Oral Tablet 60 MG	$110.58		$69.11		$0.00		$0.00		ANI PHARMACEUTICALS	N	NR	R

28. On information and belief, ANI's customers—including drug wholesalers and retail pharmacy chains—have relied on ANI's labeling, advertising, and promotion, including that which it communicates through the drug information databases, to similarly link ANI's Generic Thyroid Tablets to NP Thyroid® in their own databases.[2]

29. In addition, on its own website, ANI urges consumers to "Check prices with GoodRx," a third-party website that also advertises ANI's Generic Thyroid Tablets

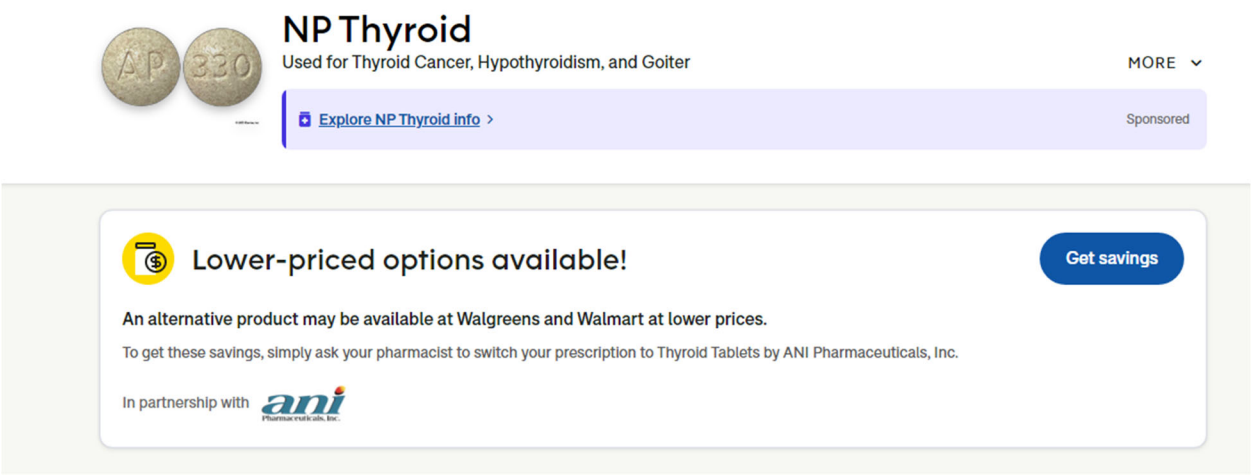


(https://www.anipharmaceuticals.com/products-detail.php?group=Thyroid+Tablets

[2]Much of the marketing of a generic drug occurs "under the radar" in targeted communications with drug wholesalers, retailers and others, who are encouraged to link equivalent products in their own databases. Like the rest of the consuming public, Acella is not privy to those communications; however, as is typical of most marketing campaigns, for every publicly available statement or piece of information there are many unseen and unheard sales pitches and additional pieces of evidence that will only come to light through discovery.

+USP+&).

30. The GoodRx website includes information on Acella's NP Thyroid®. https://www.goodrx.com/np-thyroid. GoodRx, in "partnership" with ANI, promotes ANI's Generic Thyroid Tablets as a "Lower-priced option" and "An alternative product" compared to Acella's NP Thyroid®:



31. As a result of ANI's labeling, advertising, and promotion, including the linkages ANI caused in drug information databases, ANI's customers, including drug wholesalers and retail pharmacy chains, have purchased and stocked ANI's Generic Thyroid Tablets instead of NP Thyroid®, and pharmacists have dispensed ANI's Generic Thyroid Tablets instead of NP Thyroid®; and patients have purchased and taken ANI's Generic Thyroid Tablets instead of NP Thyroid®.

F. Testing Proves that ANI's Generic Thyroid Tablets Does Not Meet USP's Minimum Standards and Is Not a Generic For NP Thyroid®

32. As FDA observes, high-quality natural thyroid replacement products are difficult to manufacture, particularly in light of the historic presence in the United States market of Chinese-sourced and inferior NDT. Notably, the label for ANI's Generic Thyroid

Tablets does not identify the source of its active ingredient, though in a public statement ANI concedes that some of its active pharmaceutical ingredients "are sourced from international suppliers," ANI Pharma., Inc. Form 10-K (Mar. 9, 2023) at 7. Acella thus became concerned that ANI may be formulating its Generic Thyroid Tablets with inferior, Chinese-sourced NDT, and falsely advertising its Generic Thyroid Tablets as USP compliant and as a generic for NP Thyroid®.

33. Acella commissioned third party laboratory testing of ANI's Generic Thyroid Tablets, in 30 mg, 60 mg, and 90 mg dosage strengths, to determine whether ANI's Generic Thyroid Tablets contains its labeled strengths, whether it is compliant with USP, and whether ANI can truthfully claim that its Thyroid Product is a generic for NP Thyroid®. The independent laboratory testing results demonstrate that ANI's labeling, advertising, and promotion of its products are literally false: All three dosage strengths of ANI' Generic Thyroid Tablets have well less than 90% of the labeled strength of levothyroxine. ANI's 60 mg Thyroid Tablet also contains less than 90% of the labeled strength of liothyronine; the 30 mg and 90 mg products are borderline with respect to this active ingredient, and are expected to fall below 90% of the labeled strength of liothyronine long before their expiration date.

34. ANI's advertising claims of the potency of the active ingredients in its Generic Thyroid Tablets are literally false. ANI's advertising claim that its Generic Thyroid Tablets meets USP standards is also literally false. And ANI's advertising claim that its Generic Thyroid Tablets is a generic for NP Thyroid® is literally false, deceptive, and misleading.

G. ANI's Literally False and Misleading Advertising Deceived Consumers and Injured Acella

35. ANI's literally false and misleading advertising of its Generic Thyroid Tablets as USP compliant and as a generic for NP Thyroid®, with the identical active ingredients in the identical strengths as NP Thyroid®, succeeded. ANI's customers, including drug wholesalers and retail pharmacies, purchased ANI's Generic Thyroid Tablets instead of NP Thyroid®, and pharmacists dispensed it to patients in lieu of NP Thyroid®, who bought and used ANI's Generic Thyroid Tablets instead of NP Thyroid®.

36. ANI's literally false and misleading advertising of its Generic Thyroid Tablets as USP compliant, and as a generic for NP Thyroid®, with the identical active ingredients in the identical strengths as NP Thyroid®, are material to the purchasing decisions of ANI's customers. Potency of the labeled active ingredients throughout their labeled shelf-life is an important and inherent characteristic of any drug and is particularly critical for natural thyroid replacement therapy. On information and belief, drug information databases would not have linked ANI's Generic Thyroid Tablets to NP Thyroid®, ANI's customers would not have purchased ANI's Generic Thyroid Tablets instead of NP Thyroid®, pharmacists would not have substituted ANI's Generic Thyroid Tablets in lieu of NP Thyroid®, and patients would not have purchased and taken ANI's Generic Thyroid Tablets in substitution for NP Thyroid®, had ANI truthfully labeled, advertised, and promoted its Generic Thyroid Tablets as non-compliant with USP standards, with subpotent active ingredients, and as inequivalent to NP Thyroid®.

37. Acella does not and cannot control the safety, effectiveness, or quality of the

ANI's Generic Thyroid Tablets. Because of ANI's literally false and misleading advertising of its product, patients who received ANI's Generic Thyroid Tablets in substitution for prescriptions written for NP Thyroid® and who have unfavorable experiences due to its sub-potency or other lack of equivalence are likely to think less of NP Thyroid®.

38. While ANI's literally false and misleading advertising has injured and will continue to injure Acella, it has at the same time unjustly enriched and will continue to unjustly enrich ANI. Per its public disclosures, ANI's net revenues for generic drug products increased significantly since the launch of ANI's Generic Thyroid Tablets. ANI credits its Generic Thyroid Tablets as among the "Key 2023 launches" contributing to its 33% growth in "Generic Revenues" (to $70.6 million in the third quarter of 2023). ANI Feb. 2024 Investor Presentation, https://www.sec.gov/Archives/edgar/data/1023024/000102302424000007/anipharmaceuticalsdeckfe.htm.

COUNT I
FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT, 15 U.S.C. § 1125(a)

39. Acella re-alleges and incorporates by reference the preceding paragraphs as if fully stated herein.

40. As set forth more fully above, ANI has, in interstate commerce, falsely and misleadingly advertised and promoted its Generic Thyroid Tablets, labeled as "Thyroid Tablets USP." ANI has made literally false and misleading representations of fact about its Generic Thyroid Tablets in commercial speech to customers and potential customers for the purpose of obtaining sales of its Generic Thyroid Tablets, including falsely claiming

that it is USP compliant, has the exact same active ingredients, in the exact same strengths, as Acella's NP Thyroid®, and that it is a generic to NP Thyroid®. None of this is true: ANI's Generic Thyroid Tablets contain less than 90% of their labeled strength of levothyroxine. Thus, ANI's Generic Thyroid Tablets is not USP compliant and is not a generic for Acella's NP Thyroid®.

41. ANI's literally false and misleading advertising violates Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which provides in relevant part that a "person who, or in connection with any goods or services" "uses in commerce any" "false or misleading description of fact or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable to a civil action by any person who believes that he or she is likely to be damaged by such act."

42. ANI's literally false and misleading advertising regarding its Generic Thyroid Tablets has actually deceived or has the potential to deceive customers, who have or will purchase, stock, substitute, and dispense ANI's Generic Thyroid Tablets instead of Acella's NP Thyroid®. ANI's literally false and misleading advertising regarding its Generic Thyroid Tablets is material, in that it relates to an inherent characteristic of its product and has influenced and will continue to influence customers' purchasing decision.

43. Pursuant to 15 U.S.C. § 1117, Acella is entitled to damages for ANI's Lanham Act violations, an accounting of profits made by ANI on sales of ANI's Generic Thyroid Tablets, as well as recovery of the costs of this action. In the circumstances of this

case, the Court may enhance Acella's damages, up to trebling its actual damages.

44. ANI's conduct makes this an exceptional case entitling Acella to recover its reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

45. Unless enjoined by this Court, ANI's acts will continue to irreparably injure Acella. Pursuant to 15 U.S.C. § 1116, Acella is entitled to preliminary and permanent injunctive relief to prevent ANI's continuing unlawful acts.

COUNT II
VIOLATION OF THE MINNESOTA UNFAIR TRADE PRACTICES ACT, MINN. STAT. § 325D.13

46. Acella re-alleges and incorporates by reference the preceding paragraphs as if fully stated herein.

47. Minn. Stat. § 325D.13 provides that:

> "No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise."

48. Minn. Stat. §§ 8.31, subd. 3a, and 325D.15 provide a private right of action to enforce the provisions of Minn. Stat. § 325D.13.

49. ANI has knowingly misrepresented the true quality and characteristics of ANI's Generic Thyroid Tablets, including that it is USP compliant, has the exact same active ingredients, in the exact same strengths, as Acella's NP Thyroid®, and that it is a generic for NP Thyroid®, when it is not.

50. ANI's false and misleading representations of fact and conduct have deceived or misled, or have a tendency to deceive or mislead, a substantial and appreciable segment of consumers and purchasers.

51. Upon information and belief, ANI's false and misleading representations of fact and conduct have influenced purchasing, stocking, substitution, and dispensing decisions or are likely to influence purchasing, stocking, substitution, and dispensing decisions for ANI's Generic Thyroid Tablets and Acella's NP Thyroid®.

52. By reason of ANI's false and misleading representations of fact and conduct, Acella has suffered and will continue to suffer damage to its business, reputation and goodwill.

53. Pursuant to Minn. Stat. §§ 8.31 and 325D.15, Acella is entitled to enjoin ANI's unlawful conduct as well as recover damages, costs and disbursements, and reasonable attorneys' fees.

COUNT III
VIOLATION OF THE MINNESOTA UNIFORM DECEPTIVE TRADE PRACTICES ACT, MINN. STAT. § 325D.44

54. Acella re-alleges and incorporates by reference the preceding paragraphs as if fully stated herein.

55. Minn. Stat. § 325D.44, subd. 1, provides that:

> A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person . . . .
>
> (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
>
> (3) causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another; . . .
>
> (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have; . . .

(7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another; . . .

(13) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding;

56. Minn. Stat. § 325D.45 provides a private right of action to enforce the provisions of Minn. Stat. § 325D.44.

57. In the course of its business, ANI, by and through its false and misleading representations of fact and conduct concerning the true quality and characteristics of ANI's Generic Thyroid Tablets, including that it is USP compliant, has the exact same active ingredients, in the exact same strengths, as Acella's NP Thyroid®, and that it is a generic for NP Thyroid®, when it is not, has engaged in and continues to engage in deceptive trade practices in violation of Minnesota Statute section 325D.44.

58. ANI has willfully engaged in its actions regarding ANI's Generic Thyroid Tablets, knowing them to be deceptive.

59. By reason of ANI's conduct, Acella has suffered and will continue to suffer damage to its business, reputation and goodwill.

60. Pursuant to Minn. Stat. § 325D.45, Acella is entitled to enjoin ANI's unlawful conduct as well as recover costs and reasonable attorneys' fees.

COUNT IV
VIOLATION OF THE MINNESOTA FALSE ADVERTISING ACT MINN. STAT. § 325F.67

61. Acella re-alleges and incorporates by reference the preceding paragraphs as if fully stated herein.

62. Minn. Stat. § 325F.67 provides that:

> Any person … who, with intent to sell … merchandise, … makes, publishes, disseminates, circulates, or places before the public, … in this state, in a newspaper or other publication, or in the form of a book, notice, handbill, poster, bill, label, price tag, circular, pamphlet, program, or letter, or over any radio or television station, or in any other way, an advertisement of any sort regarding merchandise, … which advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall, whether or not pecuniary or other specific damage to any person occurs as a direct result thereof, be guilty of a misdemeanor, and any such act is declared to be a public nuisance and may be enjoined as such

63. Minn. Stat. § 8.31, subd. 3a provides a private right of action to enforce the provisions of Minn. Stat. § 325F.67.

64. Through advertising, ANI has intentionally and willfully made, published, disseminated, circulated, and placed before the public advertisements containing false, deceptive, and misleading statements about ANI's Generic Thyroid Tablets in the context of commercial advertising in the State of Minnesota and elsewhere, including that ANI's Generic Thyroid Tablets is USP compliant, has the exact same active ingredients, in the exact same strengths, as Acella's NP Thyroid®, and that it is a generic for NP Thyroid®, when it is not.

65. By reason of ANI's conduct, Acella has suffered and will continue to suffer damage to its business, reputation and goodwill.

66. Pursuant to Minn. Stat. § 8.31, subd. 3a, Acella is entitled to enjoin ANI's unlawful conduct as well as damages, costs and disbursements, and reasonable attorneys' fees.

JURY DEMAND

Plaintiff Acella Pharmaceuticals, LLC, demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Acella Pharmaceuticals, LLC respectfully prays for the following relief:

A. The Court enter an order preliminarily and permanently enjoining ANI, its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, from directly or indirectly falsely or misleadingly advertising or promoting ANI's Generic Thyroid Tablets;

B. The Court enter an order preliminarily and permanently enjoining ANI, its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, from making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the advertisement, promotion, display, sale, offering for sale, manufacture, production, circulation or distribution of ANI's Generic Thyroid Tablets in such fashion as to imply or state that ANI's Generic Thyroid Tablets has characteristics or qualities it does not have, and/or that it is USP-compliant, has the exact same active ingredients, in the exact same strengths, as Acella's NP Thyroid®, and/or that it is a generic for NP Thyroid®;

C. The Court enter an order requiring ANI to take corrective action to correct any erroneous impression persons may have derived concerning the nature, characteristics or qualities of ANI's Generic Thyroid Tablets, including without limitation the placement

of corrective advertising;

D. The Court enter an order granting Acella such other relief as the Court may deem appropriate to prevent the trade and public from deriving any erroneous impression concerning the nature, characteristics, qualities or benefits of ANI's Generic Thyroid Tablets, alone or in comparison to Acella's NP Thyroid®;

E. The Court enter an order requiring ANI to pay Acella damages in an amount sufficient to compensate Acella for injury it has sustained as a consequence of ANI's unlawful acts;

F. The Court enter an order requiring ANI to pay Acella damages in the amount of Acella's actual and consequential damages resulting from ANI's false and misleading advertisements and unfair competition, and enhance those damages up to treble the amount found by the jury, pursuant to 15 U.S.C. § 1117(a), and the statutory law of the State of Minnesota;

G. An accounting be directed to determine ANI's profits resulting from its illegal activities and such profits be paid over to Acella, increased as the Court finds to be just under the circumstances of this case pursuant to 15 U.S.C. § 1117(a);

H. The Court enter an order finding that this case is an exceptional case and requiring ANI to pay all of Acella's reasonable attorneys' fees, costs and expenses, including those available under 15 U.S.C. § 1117(a), and any other applicable law;

I. The Court enter an order requiring ANI to pay Acella pre-judgment and post-judgment interest on the damages awarded;

J. The Court enter an order awarding Acella such other and further relief as the

Court deems just and equitable.

Dated: March 6, 2024

Respectfully submitted,

By: *s/Andre Hanson*

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